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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,217	03/02/2004	Els A.J.M. Goulmy	2183-4285.1US	3284

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,217	GOULMY ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

II. Claims 1-21 are pending.

Election/Restrictions

III. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-5, 9 and 21 drawn to an isolated recombinant **peptide** comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine, a vaccine and composition comprising said peptide, an analog of said peptide, classified in Class 530, subclass 328; Class 424, subclass 185.1.

2. Claims 6-8, drawn to a process of inducing tolerance for transplants to reduce the rejection and/or **Graft versus Host disease** in a subject by administering the recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine, classified in Class 424, subclass 184.1.

3. Claims 6-8, drawn to a process of inducing tolerance to treat a specific **autoimmune disease** by administering the recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine, classified in Class 424, subclass 185.1.

4. Claims 10-11, drawn to a process for producing **antibodies** comprising administering the isolated recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine to a mammal and antibodies that bind specifically to recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine, and antibodies made by said process classified in Class 530, subclass 387.1; Class 435, subclass 70.21.

5. Claims 10-11, drawn to a process for producing **T cell receptors** comprising administering the isolated recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine to a mammal and T cell receptor made by said process, classified in Class 435, subclass 7.24.

6. Claims 10-11, drawn to a process for producing **anti-idiotypic B cells** comprising administering the isolated recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine to a mammal and anti-idiotypic B cells produced by said process, classified in Class 435, subclass 70.3, 452.

7. Claims 10-11, drawn to a process for producing **anti-idiotypic T cells** comprising administering the isolated recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine to a mammal and anti-idiotypic T cells produced by said process, classified in Class 435, subclass 70.3.

8. Claims 12-20, drawn to a process for producing **cytotoxic T cells** against a minor antigen, and a cytotoxic T cells produced by administering the isolated recombinant peptide comprising VLXDDLLEA (SEQ ID NO: 1) wherein X is histidine or arginine to a mammal classified in Class 435, subclass 325, 455.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The instant specification does not disclose that these methods would be used together.

The process of groups 2-8 as claimed are all unrelated as they comprise distinct method steps, and endpoints that resulted in distinct products and demonstrate that each method has a different mode of operation. The process of treating distinct disease differs with respect to its etiology and therapeutic endpoint. Therefore, they are patentably distinct. Further, the distinct steps and products require separate and distinct searches. The inventions of Groups 2-8 have a separate status in the art as shown by their different classifications. Even though in some cases the classification is shared, a different field of search would be required based upon the

structurally distinct products recited and the various methods comprising the distinct method steps. A prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. As such, it would be burdensome to search the inventions of Groups 2-8 together.

Invention 1, and 2-8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide as claimed can be used in screening/binding assays as opposed to its use in making antibody. Therefore, they are patentably distinct.

IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
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Technology Center 1600
September 30, 2004

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